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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,250	02/17/2004	Yogendra Singh	4752-103.1 US	1479
7590	08/29/2006			EXAMINER PORTNER, VIRGINIA ALLEN
Diane Dunn McKay, Esq. Mathews, Collins, Shepherd & Gould, P.A. Suite 306 100 Thanet Circle Princeton, NJ 08540			ART UNIT 1645	PAPER NUMBER
DATE MAILED: 08/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,250	SINGH ET AL.	
	Examiner Ginny Portner	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 June 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 - 4a) Of the above claim(s) 1-6,8-25 is/are withdrawn from consideration.
- 5) Claim(s) is/are allowed.
- 6) Claim(s) is/are rejected.
- 7) Claim(s) is/are objected to.
- 8) Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

<ol style="list-style-type: none"> 1)<input type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u> </u>. 	<ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date <u> </u>. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: <u> </u>.
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DETAILED ACTION

Claims 1-25 are pending.

Claim 7 is under consideration; all other claims are herein withdrawn from consideration.

Claim Objections/Rejections Withdrawn

1. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been obviated by amendment of claim 7 into independent form.
2. Claim 7 is directed to “The gene encoding”(product of nature) has been obviated by amending the claim to recite the phrase “An isolated”.
3. ***Claim Rejections - 35 U.S.C. § 112:*** Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for depending from a withdrawn claim; for reciting the phrase “having sequence SEQ ID NO 4” which lacks antecedent basis in claim 1; and for reciting the phrase “The gene” and depends from claim 1 which is directed to a protein have been obviated through amending the claim into independent form.
4. Claim 7 rejected under 35 U.S.C. 102(b) as being anticipated by Sirard et al (June 1997) has been obviated by amending claim 7 to recite SEQ Id No 1, and not just SEQ ID No 4.

Rejections Maintained/Response to Arguments

1. The rejection of claim 7 under 35 U.S.C. 112, first paragraph *written description rejection*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention (scope) is traversed on the grounds that: "Applicant believes the claim satisfies the written description requirement", specifically, "Claim 7 is directed to an isolated gene comprising SEQ ID NO 4 which encodes the recombinant protein of SEQ ID NO 1."

2. It is the position of the examiner that the claim amendment recites the phrase "the recombinant protein having SEQ ID NO 1 and the isolated gene comprising SEQ ID NO 4", and not the combination of claim limitations used to traverse the rejection. SEQ ID NO 1 is an amino acid sequence of 735 amino acids, and SEQ ID NO 4 is a 69 nucleotide sequence which only encodes about 23 amino acids. The over all size of the claimed gene is not limited to SEQ ID NO 1, but is a gene that encodes a protein of SEQ Id NO 1 and also comprises SEQ ID NO 4, which may include a genus of sequences to the 5' and 3' to SEQ Id NO 4; as well as regulatory sequences for bacterial open reading frame operation. What the genus of sequences are, that comprise SEQ ID No 4, and is not the coding sequence for SEQ ID NO 1, has not been described. This rejection is maintained for reasons of record and responses set forth herein.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 has been amended to be directed to an isolated gene, but how many open reading frames are included in the claimed bacterial gene is unclear, as the gene encodes SEQ ID NO 1 and additionally comprises SEQ Id No 4, which a portion of a coding sequence for iota

toxin from *Clostridium perfringens*. Does the gene comprise one or two open reading frames or more. The newly submitted combination of claim limitations are unclear in light of the fact that SEQ ID NO 1, is an amino acid sequence and SEQ ID NO 4 is a polynucleotide sequence and are set forth in the claim as a combination of sequences by the recitation of the term "and" on line three of the claim. Clarification is requested.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
August 21, 2006

LYNETTE R. F. SMITH
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